

# EXHIBIT Q

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI

*BAYES, et al v. BIOMET, INC., et  
al.*

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CAUSENO.

4:13-cv-00800

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**REBUTTAL EXPERT REPORT OF GEORGE S. KANTOR, M.D.**

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## **I. QUALIFICATIONS**

Attached as Exhibit "A" and incorporated into this Expert Report is my current *Curriculum Vitae* which reflects my education, training, awards, publications, experience, and qualifications in the area of orthopedic surgery.

I received my Bachelor of Arts Degree in 1971 from Tulane University, New Orleans, Louisiana with high honors. I received my Medical degree from Tulane University in 1977. Following a one-year flexible surgical internship at Charity Hospital, Tulane University I matriculated to the University of Utah from 1978-1982 where I completed my Orthopedic residency. This was followed by an 18-month post-Doctoral fellowship at the University of Southern California in Los Angeles focusing on Adult Reconstructive/Joint Replacement surgery. I have been Board Certified by The American Board of Orthopedic Surgery since 1986 with ABOS recertification in 1998 and 2009. My recertification status runs through 2020. All certifications were passed during the first sitting.

My professional honors include, but are not limited to, Bachelor of Arts with high honors 1971, Tulane University; "Golden Scalpel" award for outstanding surgical intern, Charity Hospital/Tulane University from 1977 -1978; Chief resident University of Utah from 1981-1982; and Albert E. Klinkicht award from American Academy of Orthopedic Surgery/American Orthopedic Foot Society in 1981.

Additionally, I've held the following appointments and/or positions in during my

career: Johnson and Johnson Orthopedics, Inc., Clinical Consultant and Surgical Instructor from 1990-1997; DePuy Orthopaedics, Inc., Clinical Consultant and Surgical Instructor from 1997-2009; M.D. Network, Medical Director/Consultant, Physical Therapy/Occupational Therapy and Rehabilitation from 1997- 2005; The Gardens Court, Medical Director of Rehabilitation from 2001- 2005; Chatsworth at PGA National, Medical Director of Rehabilitation from 2001-2011; The Waterford, Medical Director of Rehabilitation from 2011-2012; Chairman Dept. of Orthopaedics, Palm Beach Gardens Medical Center from 1998-1999 and 2002- 2004; Chairman Dept. of Orthopaedics, St. Mary's Medical Center from 2008-2015; Vice Chief of Staff, Palm Beach Gardens Medical Center from 2000-2002; Vice Chief of Surgery, Palm Beach Gardens Medical Center from 2000-2002; Palm Beach Gardens Medical Center, Medical Council from 2000-2002; Spokesperson, Tenet Southeast Regional Total Joint Program from 1996-2012; Presidential Advisory Council Tulane University from 2008- present; and Governing Board of Directors Tulane University Medical School from 2011-present.

Following my fellowship training, I have been in private practice for 35 years at the at the same office and locale specializing exclusively in joint replacement of the hip, knee and shoulder. Once in practice I took part in visiting surgeon visits

to the United Kingdom on a regular basis. Since the inception of my private practice in Florida, I have performed approximately 12,000 total Joint procedures, 5,000 of these procedures involved total hip arthroplasty. Approximately 25-30% of my practice has involved complex revision procedures.

## **II. ASSIGNMENT**

I am being designated as an expert in the field of orthopaedic surgery for purposes of analyzing and critiquing specific causation opinions rendered by Biomet, Inc.'s designated experts. In analyzing Biomet, Inc.'s designated experts' opinions, I have rendered contradictory conclusions as to specific causation of Mary's Bayes' injuries stemming from the 2008 implantation of bilateral Biomet M2A Magnum Hip Systems. I have already been designated as an expert in the fields of medicine and orthopaedic surgery. As stated in my expert report on general causation, I will also provide fact and/or opinion testimony regarding the concept, development, design and performance of the metal-on-metal bearing surfaces, including those manufactured by Biomet Orthopedics, Inc., et al. (Biomet). I will also give general opinions regarding damages and/or injuries that may occur due to of metal on metal bearing surface failures. I reserve the right to supplement this report when further data, documents, records or information becomes available, in order to update, revise or correct this report if necessary. I may use visual aids or demonstrative exhibits that illustrate or explain my opinions.

### **III. MATERIALS REVIEWED**

A list of the materials, including scientific and medical publications, facts or data, and internal Biomet and third-party documents, that I reviewed in preparing this report is attached as Exhibit "B."

In preparation of the rebuttal report on patient Mary Bayes, I have reviewed reports written by Dr. Fleeter, Dr. Bauer, and Dr. Kurtz, along with the history and physical and operative reports of nine major surgical procedures performed on the left and right hip articulations. These include the right index or primary THA and one revision procedure as well as the left index THA and six revision procedures. I have also reviewed radiographic studies involving these surgical procedures and hospitalizations as well as serologic studies and pathology reports. In addition, I have reviewed the records of sixteen hospital admissions for the treatment of dislocations of the left THA requiring various types of anesthesia administered for reduction of those dislocations. Most important at arriving at my conclusions, which directly contradict those of Dr. Fleeter, is review of multiple intraoperative photographs taken on 3/28/2011 by Dr. Lux at the first revision procedure performed on the left THA. These photos clearly demonstrate to even the lay person the extensive tissue destruction and necrosis caused by metal ion debris caused by the Biomet THA construct. This is similar to what I have encountered in the hundreds of MoM total hip arthroplasty revisions that I have

been involved in personally. I have also reviewed the depositions of treating revision surgeons Drs. Lux, Nunley, and Mudd.

#### **IV. OPINIONS**

##### **A. Knowledge of the History of Metal on Metal total hip replacements**

Knowledge and insight, I gained during my training and early experience led me to the professional opinion, developed long ago through my professional training, education, and experience, that the risk of employing metal-on-metal (MoM) bearings for either primary or revision hip arthroplasty far outweighed any supposed benefit. I continue to hold that opinion today.

Dr. Phillip W. Wiles, a British surgeon, performed one of the first MoM bearing surface total hip arthroplasty (THA) in 1938. In the years that followed, additional MoM bearing systems were developed such as the Ring and McKee-Farrar implant systems. These early MoM hip systems have been widely referred to as the "first generation" MoM hip implants. These first-generation MoM implants failed at an unacceptable rate. The published failure rates of the designing surgeons of first-generation MoM THA systems including McKee, Ring, Stanmore and as well as others is unacceptable by our current established standards and was the primary reason for the discontinuation of MoM bearing

surfaces in THA. They did not reproducibly and reliably provide a long lasting, pain free functional hip articulation for patients. Additionally, adverse bone and soft tissue reactions were common with these MoM prostheses. Revision surgical procedures for failed first generation MoM hip prosthesis were extremely difficult, surgically challenging and often resulted in poor outcomes. Long-term follow-up of this relatively small number of patients implanted with first generation MOM hip implants was minimal and often anecdotal; however, there was evidence suggesting metal wear debris from these MOM devices caused local and systemic harm to the patients, including the potential risk of carcinogenicity leading to premature failure of the devices, the need for revision surgery, and other serious harm.

In November of 1962, Dr. John Charnley performed the first total hip arthroplasty (THA) utilizing a stainless-steel femoral component and high molecular weight polyethylene (HMWP) acetabular component. This construct was the birth of the modern total joint arthroplasty. Metal on polyethylene (MoP) became the standard in THA procedures and it remains the standard today. With the new design and material changes, Dr. Charnley called the new and improved operation a "low friction torque arthroplasty." He waited approximately 5 years before confirming and announcing to the orthopedic community in 1967, the success of his MoP discovery and the successful results of the MoP surgical

procedures. The surgical principles of smaller metal heads and selection of the polyethylene bearing surface material continues to be one of the most efficacious and safest THA option to date and far preferable to the use of MOM bearing surfaces as the risks of those devices outweigh their benefits for the patient. The success, longevity, efficacy and safety of the MoP procedure have been well documented and proven over several decades. To date, there are multiple 20 and 30-year studies that confirm Chamley's "low friction torque arthroplasty" success utilizing a small metal femoral head and polyethylene acetabular component.

Even with the comparative success of the MoP articulations, the old polyethylene bearing surfaces experienced some wear resulting in polyethylene debris. However, the development of better polyethylene, including highly cross-linked polyethylene during the 1990s and its widespread adoption into the early 2000s, adequately addressed the concerns over polyethylene wear, rendering MoP hip implants a safer and more appropriate implant than MoM hip implants. Medical literature documents the long-term wear properties associated with highly cross-linked polyethylene and the significantly decreased risks to the patient compared to the MoM hip constructs. From 2000 to date, approximately 6 million total hip arthroplasty surgeries have been successfully performed worldwide utilizing cross-linked polyethylene. The risk versus

benefit of MoM bearing surface components versus either MoP with highly cross-linked polyethylene or ceramic on polyethylene (CoP) bearing surfaces, in my experience, highly favors the MoP and CoP bearing surface construct over the MoM bearing surface couplings, which includes the Biomet M2A devices.

My surgical training with hip implants started during my residency at the University of Utah in 1978 and continued through the completion of my additional post-doctorate fellowship training in joint replacement and adult reconstructive surgery at the University of Southern California in 1984. Because of my interest in joint replacement surgery as an orthopedic sub-specialty, I was directly involved in approximately 150 revision surgeries of first-generation MoM systems. These included: (1) Ring THAs, (2) McKee-Farrar THAs, and (3) Stanmore THAs. My extensive exposure to these systems occurred because the primary surgeons responsible for these implantations were the professors that I had the privilege of training under. These surgeons were my mentors and friends including, Sherman S. Coleman, M.D. and Augusto Sarmiento, M.D., both past presidents of the American Academy of Orthopedic Surgeons and founding members of the International and American Hip Societies. Other mentors that helped to shape my perspective on THA, material bearing surfaces, and the surgical implantation of hip devices include, but are not limited to, Harold Dunn, M.D., Wallace Hess, M.D., Lawrence Dorr, M.D., Michael

Freeman, M.D. and Robin Ling, M.D. Some of these above physicians are also International and/or American Hip Society members and all are respected pioneers in the development and use of THA.

My association with the above-referenced physicians, along with my consultation duties for J&J and DePuy, has allowed me the opportunity to collaborate with biomaterial experts, including but not limited to, Harry McKellop, Richard Tarr, Ian Clark, Thomas Gruen, Allen Daniels, Roy Bloebaum and Johnathon Black all of whom are well-respected in their field and have expertise with regard to materials science and implant designs. Through my working relationship with these individuals, I gained an appreciation and understanding of biomaterials in total joint arthroplasty. My experience with the above surgeons and biomaterial experts, along with my own practice involved the care and surgical treatment of first generation revisions/failures and subsequently second generation MoM hip revisions/failures in MoM hip patients. This experience also involves numerous explant laboratory analyses following implant removal post-revision. During the course of my consultant work with DePuy in the early 2000s, I also expressed my concerns to that medical device manufacturer about the safety and efficacy with the reintroduction of MoM bearing surfaces for THA systems without clinical trials considering our knowledge of first-generation MoM system failures.

The late 1990s and early 2000s saw the re-introduction of MoM

hip systems in the form of "second generation" MoM total hip replacement (THR) and resurfacing arthroplasty components. The Biomet MoM hip implants that are the subject of this litigation would be considered part of this "second generation." Over the more than three decades before this re-introduction, traditional non-MoM bearing surface THRs consistently performed better than the first-generation MoM THAs. Because of my training, research, and personal experiences with the revisions/failures of the first generation MoM hip systems, I have never performed a primary/index MoM THA with any of the second generation MoM hip systems, including the Biomet MoM products at issue here, as it was, and continues to be my opinion as a fellowship trained orthopedic surgeon specializing in THA surgery that the risks of use of these MoM devices outweighs their benefits for patients. In particular, the biological risks associated with the generation and production of metal particulate wear debris made me question the safety and efficacy of MoM articulations compared to safer and proven material couplings (i.e.: MoP or CoP). I was also concerned about the lack of long- term safety and efficacy data from Biomet and other manufacturers of MoM devices with regard to the performance of the devices in patients as well as long-term risks of the cobalt-chromium bearing surface and trunnion interfaces.

My long-held concerns about the safety and efficacy of MoM hip

implants has been borne out by numerous studies published over the last few years, updated patient safety information from government regulatory agencies, data from international joint registries, poor patient outcomes documented in my own practice and those of my colleagues (which have been the subject of discussions at professional meetings and various publications), and the fact that many of these MoM products have been formally recalled or are no longer sold.

It is my opinion that the Instructions for Use for the Biomet MoM hip implants, as changed over time, provided insufficient information to orthopedic surgeons to allow them to fully evaluate the risks versus benefits of the Biomet MoM hip implants and make proper recommendations to their patients. It is further my belief that manufacturers of MoM hip implants, including the Biomet MoM hip implants, conducted an insufficient number of studies of the long-term safety of the MoM hip implants to provide adequate information to orthopedic surgeons and patients about the risks versus the utility of the MoM hip implant designs to allow surgeons and patients to make adequate decisions about treatment options and the appropriate devices to be utilized for hip implant procedures from the late 1990s to the present when "second generation" MoM hip implant designs were being sold by Biomet and other medical device manufacturers. Knowledge of the special risks associated with MoM hip implant designs was certainly knowable for the medical device manufacturers such as

Biomet during the time period just before and during the marketing of second-generation MoM hip implants, but was not well-known to many practicing orthopedic surgeons, especially those who did not train with surgeons, such as I did, with personal experience relating to early failures of MoM devices.

From the outset of my surgical training to date, I have, time and again, personally seen the negative impact of significant and catastrophic musculoskeletal damage and systemic complications caused by the use MoM hip arthroplasty systems. This is now accepted scientific fact, well documented in the orthopedic literature. Specifically, prosthetic-generated metallic wear debris can destroy the soft tissues (i.e.: capsule, tendon/ligament, and muscle), as well as the bony foundation to the hip joint (for example, the pelvis and femur) in implanted patients which leads to pain, poor performance of the MoM hip implant, the need for revision surgeries, and the chance that the patient will have less than optimal results from future hip implant surgeries due to bone and tissue damage caused by the MoM device. Of equal or greater concern are the systemic consequences that can result from the use of MoM bearing surfaces and the metal ion particulate debris they produce in the human body. The risks to patients from metal ion particulate debris is still not well understood due to a lack of definitive studies and testing performed by the manufacturers of the MoM devices, including Biomet, prior to introduction of the products to the market and

implantation in patients. These include the development of related malignancies and bone and tissue damage, which I have witnessed first-hand and which is documented in the published, peer-reviewed scientific and medical literature.

**B. Personal Experience with Second Generation MoM hip systems**

I have never implanted any MoM articulating coupling as a primary hip implant in my patients due to my longstanding concerns about the safety and efficacy of MoM devices, such as the MoM hip implants manufactured by Biomet. However, I have performed removal/revision surgery on patients with various failed MoM bearings, including the Biomet MoM bearing systems. I have also treated patients who suffer from the multiple complications secondary to the damage caused by MoM articulating interfaces. These complications are very similar to what my early training, research, and personal experiences had been with the revisions/failures of the first-generation MoM hip systems.

Because I avoided using the second-generation MoM hip implant systems such as the Biomet MoM options, coupled with my satisfaction and success using pre and post-cross-linked MoP and/or CoP in my patients, my experience with the MoM devices occurred when patients presented for revisions or clinical follow-up upon referral. In my practice, I started evaluating and treating various patients with MoM implants and their complications, in approximately 2006 and continue to see them today.

In my experience, the primary presenting symptom in MoM hip patients is pain and discomfort. This is often accompanied by decreased activity and in many cases the reliance on and necessity of ambulatory assist devices, such as a cane, crutch, or walker/wheelchair. These patients exhibit a gait abnormality that is not only antalgic (i.e., pain producing), but also reflects muscle deficiency that most often and specifically targets the abductor muscle group (the muscle group that is essential to the proper functioning of the THA). This results in a distinctive gait disturbance/abnormality in MoM patients. Patients also frequently present with varying degrees of swelling of the involved extremity. This can vary from subtle to severe and can be noted in the foot and ankle extending all the way to the knee and/or upper thigh. This swelling which is due to obstruction of the vascular supply to the lower extremity is often accompanied by the finding of asymmetrical pulses in the foot and ankle.

Patients can present with complaints of pain in the knee, thigh, lumbar spine, and sacroiliac joint regions, which typically has its root cause at the hip articulation. This presentation at the initiation of the patient's symptoms can be non-specific, nebulous and distract the examiner from the true origin of the pain as it is being referred from the hip articulation. It is not uncommon for patients who are exhibiting signs of failure of their MoM hip implants to be treated for back or knee pain without addressing the hip implant-related issues due to

this confusing presentation of symptoms. Biomet, as well as the other MoM manufacturers, have failed to provide appropriate instructions and warnings to orthopedic surgeons of the signs and symptoms associated with failure of their MoM devices as well as protocol for ongoing monitoring of patients, which contributed to a delay in proper treatment for the failure of some patient's MoM devices.

With these patients, a radiographic analysis including plain films, ultrasound studies, CT scans, and special MRIs routinely demonstrate osteolysis/osteonecrosis, prosthetic loosening, pseudotumors, and/or pathological fractures. Serology (i.e.: blood testing) can demonstrate varying degrees of abnormal elevations of circulating metal ions, including cobalt and chromium. However, metal ion concentration in serum and whole blood are not reflective of the true metal ion concentrations found in the hip articulations or in concentrations in the soft tissues juxtaposed to the prosthesis/implant. It has been shown that the true metal ion levels are exponentially higher and one hundred times greater than what is reflected in the serum or whole blood. Quantitative analysis in excised diseased soft tissue juxtaposed to the total hip arthroplasty also confirm the high ion concentrations. Once soft tissue (capsule, ligament, tendon, and muscle) destruction occurs, it is irreversible and can result in instability manifested by dislocation of the hip articulation. There is an

increased risk of multiple complications following a revision surgery, including but not limited to infection and dislocations.

When MoM implant failure occurs in this manner, necrosis of the bone, tendons and tissue can be a direct result of the premature failure of the device. This outcome can result in permanent damage to the bone and soft tissues adjacent to the patient's implant, which is irreversible.

Complications resulting from the premature failure of the MoM implants, such as the Biomet MoM hip implants, include the likelihood of a patient needing multiple future revision surgeries with increasing complexities of those revision procedures to be expected, especially in light of the bone and tissue damage that often accompany the failure of a MoM hip implant. In comparison to MoP or CoP alternatives, there is a significantly increased risk of dislocations, infections, and peri-prosthetic pathologic fractures published in multiple joint registries in countries following the sub set of MoM prosthetic implant systems. Hip instability and multiple dislocations as experienced by Mrs. Bayes has an extremely poor prognosis that is unsolvable by even skilled revision surgeons.

The majority of failed MoM bearing cases that I have personally evaluated clinically or during surgical revision reveal proper and acceptable component positioning. The prognosis for patients with osteolysis/osteonecrosis, soft tissue destruction, and pathological fracture

associated with their implantation with a MoM hip implant is extremely poor.

I have been involved with over 100 "second generation" revisions as well as numerous "first generation" revision surgical procedures of MoM hip systems during my career as a Board-certified orthopedic surgeon. In my practice, the use of cross-linked polyethylene with either MoP or CoP has resulted in an extremely low revision rate, and is a far safer and more efficacious alternative to the use of MoM hip implant designs, including the Biomet MoM hip implants at issue here. I have not performed a single revision procedure for wear of a cross linked poly acetabular component in over a decade.

I hold each of the stated opinions to a reasonable degree of legal, medical and surgical probability.

## **V. CASE SPECIFIC HISTORY OF MARY BAYES**

Mrs. Mary Bayes developed progressive degenerative joint disease/osteoarthritis to her hip articulations in her late fifties. She was initially and appropriately treated with various modalities including anti inflammatory medications, intra articular injections, and activity modification and exercises without relief. With worsening and progression of her symptoms and arthritic condition respectively and with significant compromise to her activities of daily living she elected to undergo THA. Dr. Daniel Martin selected the Biomet M2a

THA system which utilizes MoM bearing surfaces at the artificial joint articulation in conjunction with large head mixed metal femoral modular components. The initial index THA procedures were performed on January 14, 2008 on the right hip and April 25, 2008 on the left hip. X-ray analysis measured on multiple post-operative film studies revealed appropriate component positioning and excellent placement of both the femoral and acetabular components. On the acetabular side her right abduction angle was measured at 48 degrees and 40 degrees on the left. Her femoral components exhibited excellent canal fill and placement. There is no evidence on component malposition to her index total hip arthroplasties performed by Dr. Martin.

Her immediate post-operative course and rehab was uneventful and uncomplicated and resulted in the resolution of all of her pre-operative symptoms. By 6 months following each surgical procedure she was walking without pain, without limp and resumed her normal activities without restriction or compromise.

In early 2010 approximately 2 years after her bilateral THA procedures, she began to experience pain in her left buttocks, left groin and lumbar spine. She subsequently underwent multi-level lumbar spine surgery without relief of the aforementioned symptoms. By late 2010 her left hip pain had progressed, her ambulatory status diminished and she was walking with a pronounce antalgic limp.

Mrs. Bayes subsequently consulted Dr. Paul Lux, a fellowship trained hip specialist in January 2011. After work up and evaluation, Dr. Lux performed revision to her left MoM THA. Critical to the understanding of the cause of Mrs. Bayes problems at the time of her first revision and her problems to this day are the dramatic and disturbing intra operative photos taken by Dr. Lux at revision number one. These photos demonstrate extensive tissue necrosis/death of the entire capsule, short muscular rotators and substantial portion of the abductor muscles group. There is clearly an organized and aggressive reactive “pseudotumor” causing the destruction to the multiple and critical portions of the hip articulation specifically the hip capsule, rotator musculature, and the abductor muscles. This necrosis and tissue destruction is progressive and irreversible in spite of Dr. Lux efforts.

Mrs. Bayes post-operative course following revision number one through revision number 6 is sadly typical of metal ion debris destruction. This disease process has been termed metallosis. Mrs. Bayes has undergone a total of 6 complex revision procedures performed by 3 experienced, fellowship trained hip specialist without resolution of her debilitating condition which is joint instability causing multiple dislocations of her THA. Besides her 6 revision surgeries she has experienced at least 11 dislocations requiring hospitalization, anesthesia administration and non-surgical manipulation of her THA. Her last dislocation in

May 2019 occurred while at church. Mrs. Bayes has also undergone in addition to the 6 revision procedures on her left hip an appropriate and timely revision of her index right THA by Dr. Nunley on July 8, 2014. This operative procedure was undertaken to remove the index MoM THA on the right in an effort to prevent further tissue destruction experienced on the left THA.

Mrs. Bayes has been subjected to every type of revision procedure utilizing revision hip systems specifically designed for the prevention of dislocation. These procedures have been appropriately selected and properly executed by her surgeons. They include traditional revision THA constructs, semi constrained constructs, multiple constrained THA systems as well as multiple dual mobility systems. None of these however have prevented recurrent dislocations. Unfortunately, there is no surgical treatments in the revision surgeon's armamentarium that will provide Mrs. Bayes with a stable, functional THA and prevent dislocation.

## **VI. ANALYSIS OF DR. FLEETER'S OPINIONS AND CONCLUSIONS**

**In analyzing Dr. Fleeter's opinions as stated in his report in the Bayes matter and rendering my opinions in rebuttal, I utilized the research noted in this report, my clinical experiences, the information discussed above, and**

**the documents listed in Exhibit B. All rendered opinions are done to a reasonable degree of medical certainty. Paragraphs cited to reference paragraphs in the “Opinions” section of Dr. Fleeter’s report.**

Bilateral THAs were the appropriate treatment for Mrs. Bayes end stage osteoarthritis to her hip articulations. The defective Biomet M2a design however is the cause of the failure of the implants. She was an ideal candidate for hip replacement and had no contraindications to those operations in her medical history. Her initial procedures were done without complication and the artificial components were implanted in acceptable position with no evidence of malposition. Her recovery was routine and uneventful and there was rapid and complete resolution of her pre-operative symptoms. Mrs. Bayes experienced progressive pain and difficulty with ambulation within approximately 18 months of her left THA. Her physical examination and workup including multiple radiographic studies by Drs. Martin and Lux are typical of metal ion disease generated by her Biomet THA. It is important to note that CT studies performed in September and October with aspiration clearly indicate and confirm involvement of the iliopsoas muscle tendon group which is also indicative and the hallmark of dissemination of the toxic metal ions from her hip spreading beyond the hip articulation. This spread of her metal ion debris into the inner pelvis is also a typical presenting finding on examination and obviously troubling and

worrisome.

In paragraph number 2 of Dr. Fleeter's opinions he is incorrect and obviously does not understand the definition of "metalosis", "pseudotumors" and their relationship. By definition, metalosis is metal (ion) disease just as nephrosis is defined as kidney disease. Metal ion debris originating and disseminating from Biomet's THA systems are responsible and the cause of the toxic destruction of Mrs. Bayes hip articulations specifically the left. The reactive and necrotic tissue visualized in the four photos taken at revision number one of the left hip are caused by microscopic metal ion debris and is an example of metalosis at its worst. These photos clearly demonstrate the well developed pseudotumor and the destructive tissue and reactive tissue surrounding it. It is the toxicity of these metal ions in concentration and the response they generate in the body that is the cause of the tissue death. This surgical finding is appropriately described by Dr. Lux in his operative report and summary letter. Although Dr. Fleeter exhibits a lack of understanding of the disease process and its terminology involved in this case, he does recognize in the same paragraph the complete loss and destruction of the abductor musculature which is the primary stabilizer of the hip articulation and states in his last sentence "this finding is not reconstructable". In paragraph number 3 Dr. Fleeter opines that constrained THA constructs are a solution including a long-term solution. This is obviously not true as evidenced by Mrs.

Bayes revision history. She has dislocated her left hip articulation on multiple occasions where various constrained THA constructs were implanted by multiple revision surgeons in the hope of preventing dislocation. This has also been my personal experience, (shared by my colleagues who perform revision surgeries) and I have multiple examples in my practice of failure of constrained devices used to prevent dislocation in metal related revision procedures. The failure to prevent dislocations with constrained systems has been reported at tertiary care centers dealing with these complex cases. Dr. Fleeter's statement that Mrs. Bayes has abductor weakness is also incorrect and an understatement of fact. The only other muscle capable of providing minimal abduction is the tensor fasciae latae. It has been shown that abductor force generated by this muscle is minimal and not capable in providing abduction force to prevent dislocation. Dr. Fleeter also states in the same paragraph that muscle transfer from the gluteus maximus to the greater trochanter has been helpful and "remarkably effective". It should be noted that none of the skilled revision surgeons including Dr. Lewelyn, who evaluated Mrs. Bayes in consultation, has attempted this approach. I am certain that Dr. Fleeter has not performed this procedure, and I am unsure if he has done a revision involving metalosis. I am unaware of any published reports confirming his statement for the treatment of chronic instability and dislocation associated with metal ion disease related revisions. In my own practice this procedure as well as

allograph tendon reconstruction has not been effective in providing stability and preventing dislocation. I have however utilized this transfer technique with some success for chronic positional dislocations in non-metal related disease revisions.

In paragraph 3, I find it extremely disturbing that Mrs. Bayes because of “certain activities” is in any way responsible for her hip instability, repeat dislocations and the prevention of same. Any resident in training is aware that THA patients can resume normal activities of daily living at the six-month post op interval following successful THA. Tying one’s shoes and going to church would certainly be acceptable activities in the normal THA population. It is well known to orthopedists performing THA that it is almost impossible to dislocate a properly functioning THA after the 6-month post op interval and certainly 1 year following THA. Mrs. Bayes did not sustain any dislocations prior to her revision on March 28, 2011. She is fortunate that her initial presentation for revision surgery was in fact not a dislocation. Patients often are referred to our office and to offices in institutions of revision surgeons with dislocations prior to their first revision.

Regarding paragraphs 4 and 5, Mrs. Bayes index THA were implanted properly and her abduction angles were acceptable. I took measurements of the 2008 left-hip post surgical x-ray, which showed a 40 degree abduction. 40 degrees is within the recommended range of implantation. There is no demonstration of component malposition in either hip and malpositioning of the Biomet M2A

System by Dr. Martin is not a factor in Mrs. Bayes' subsequent injuries.

## **VII. SUMMARY**

The failure of the left and right Biomet THAs is caused by design defect. Material selection as it relates to bearing surfaces as well as mixed metal trunnion couplings are present in this system and are design specific defects. Sir John Charnly the father of modern total hip arthroplasty surgery stated that the three things required for a successful THA system are

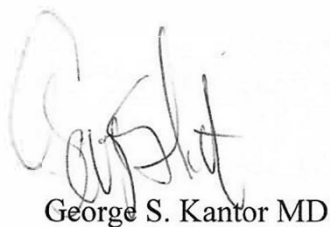
1. Design which includes material selection
2. Component positioning
3. Fixation of the artificial components to bone.

The orthopedic community has deviated from these basic principles and have turned the “operation of the century” (20<sup>th</sup>) into the disaster of the 21<sup>st</sup>. A Global Tribology Summit was convened at the Hospital for Special Surgery in February 2017 to address metal related disease in THA. The position of participants was “Stemmed Metal on Metal Total Hip Arthroplasty should be avoided in all patient populations”. The use of MoM bearing surfaces in 2<sup>nd</sup> generation stemmed THA especially used in conjunction with large head mixed metal modular couplings has resulted in an epidemic of complications. The design and material selections for the Biomet hip used for Mrs. Bayes index surgery disregarded basic established scientific facts regarding mechanical, material and

electrochemical considerations and are solely responsible for the failure of her THA.

In closing Mrs. Bayes post-operative complications are not unique or rare and are being experienced by thousands of patients currently. She is in no way responsible for her current condition and unfortunately there is no remedy or solution to resolve her ongoing medical condition as it relates to her left hip articulation. At the time of this writing Mrs. Bayes has undergone 9 major hip procedures, 2 of these procedures were her initial right and left hip replacements. As a result of the complications from her initial surgeries, she has undergone 7 complex revision surgeries-1 to the right and 6 to the left without resolution. She has been additionally hospitalized and treated at least 11 occasions for dislocations and I have counted over 100 physicians; treating surgeons, orthopedic treating physicians, anesthesiologists, emergency room physicians and consultants who have taken part in her care. Unfortunately, her problems are ongoing and without remedy. Contrary to Dr. Fleeter's opinions, the defective design of the Biomet M2A system is the cause of Mary's Bayes' hip injuries post-implantation of the device. These injuries include, but are not limited to: destruction of capsule, tendon, and muscle, as well as bone, which has resulted in pain, repeat and multiple dislocations due to instability, inability to ambulate, and have adversely affected the patient's quality of life. The defective design led to the release of

metal ions into Mrs. Bayes' tissue. The metal ions generated by the Biomet M2A Magnum Hip System are toxic to healthy tissue, and led to tissue death for Mary Bayes.



George S. Kantor MD

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**EXHIBIT "A" TO EXPERT REPORT OF GEORGES. KANTOR,  
M.D. -**

*CURRICULUM VITAE*

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## **CURRICULUM VITAE**

**GEORGE S. KANTOR, M.D.**

### **PERSONAL BACKGROUND AND INFORMATION**

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(September 1983 - present)

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DATE OF BIRTH: March 8, 1949

PLACE OF BIRTH: Yonkers, New York

CITIZENSHIP: United States

### **EDUCATION AND DEGREES**

HIGH SCHOOL: Peekskill Academy  
Peekskill, New York (1967)

COLLEGE: Tulane University  
New Orleans, Louisiana  
(B. A., 1971) [1967-1971]

MEDICAL SCHOOL: Tulane University  
New Orleans, Louisiana  
(M. D., 1977) [1973-1977]

INTERNSHIP: Tulane University  
New Orleans, Louisiana  
Flexible Surgical Internship  
[1977-1978]

RESIDENCY: University of Utah  
Salt Lake City, Utah  
Orthopaedic Residency  
[1978-1982]

FELLOWSHIP:

University of Southern California  
Los Angeles, California  
Adult Reconstruction/Arthritis Surgery  
[1982-1983]

**LICENSURE/CERTIFICATION**

FLORIDA MEDICAL LICENSE

ME0042161

BOARD CERTIFICATION

American Board of Orthopaedic Surgery  
1986 (Acceptance at first sitting)

ABOS Recertification, July 1998

ABOS Recertification, July 2009

ABOS Recertification through 12/31/20

**MEDICAL HONORS AND AWARDS**

"Golden Scalpel Award" for Outstanding Surgical Intern, Charity Hospital, 1977-1978

"Albert E. Klinkicht Award," American Orthopaedic Foot Surgery, 1981

Chief Resident, University of Utah, Orthopaedic Residency, 1981-1982

**HONORS AND AWARDS**

Reisch Tumisha Scholarship, Academic/Athletic Excellence, Westchester County, 1967

Varsity Football, Tulane University, New Orleans, Louisiana, 1969-1970

Deans List, Tulane University; 1969, Spring Semester, 1971, Spring Semester, named consecutively

B. A. Tulane University with High Honors

**PRESENTATIONS**

Investigation of Lateral Ligament Reconstruction, American Academy of Orthopaedic Surgeons, Las Vegas, Nevada, 1981.

Pelvic Osteotomy for the Treatment of Adolescent Hip Dysplasia, Shrine Hospitals Scientific Meetings, Salt Lake City, Utah, 1982.

Histomorphometric Analysis of Bone, Western Orthopaedic Society, 1993.

Salter Osteotomy for the Treatment of Acetabular Dysplasia in the Adolescent, American Academy of Orthopaedic Surgeons, Atlanta, Georgia, 1984.

Resection Arthroplasty for Infected Total Hip Arthroplasty, American Academy of Orthopaedic Surgeons, Las Vegas, Nevada, 1985.

The Girdlestone Hip Following Infected Total Hip Arthroplasty, Florida Orthopaedic Society, Key Largo, Florida, 1987.

## **PUBLICATIONS**

Horstman, J.K., Kantor, G.S., and Samuelson, R.M.; "Investigation of Lateral Ankle Reconstruction," Foot and Ankle, November 1981.

Kantor, G.S., Dorr, L.D., and Malluche, H.; "Histomorphometric Analysis of Bone Adjacent to Cemented Femoral Prosthesis in Rheumatoid and Osteoarthritis," Clinical Orthopaedic, No. 205, May 11, 1985.

Kantor, G.S., Osterkamp, J.A., Dorr, L.D., Fischer, D., Perry, J., Conaty, J.P.; "Resection Arthroplasty Following Infected Total Hip Replacement Arthroplasty," The Journal of Arthroplasty, Volume 1, Number 2, October 1986.

Kantor, G.S., Coleman, S.S.; "Salter Osteotomy for the Treatment of Acetabular Dysplasia in the Adolescent," The Journal of Bone and Joint Surgery

Kantor, George S., M.D., Hartrick, Craig, M.D., DABPM, FIPP, Durieux, Marcel E., M.D., Ph.D., Gould, Errol M., Ph. D.; "Extended -Release Epidural Morphine for Pain after Total Hip Arthroplasty," The Journal of Bone and Joint Surgery, 2004.

Hartrick, Craig, M.D., Martin, Gavin, M.D., Kantor, George, M.D., Koncelik, John, D.O., Manvelian, Garen, M.D.; "Evaluation of DepoDur, A Single-Dose, Extended- Release Epidural Morphine Formulation for Pain After Knee Arthroplasty," The Journal of Bone and Joint Surgery, 2005.

## **APPOINTMENT/POSITIONS**

Johnson and Johnson Orthopedics, Inc. Clinical Consultant and Surgical Instructor 1990-1997.

DePuy Orthopaedics, Inc., Clinical Consultant and Surgical Instructor 1997-2009.

M. D. Network, Medical Director/Consultant, Physical Therapy/Occupational Therapy and Rehabilitation, 1997-January 2005

The Gardens Court, Medical Director of Rehabilitation, 2001-December 2005

Chatsworth at PGA National, Medical Director of Rehabilitation, August 2001-2011

The Waterford, Medical Director of Rehabilitation December 2011-2012

Chainnan Dept. of Orthopaedics, Palm Beach Gardens Medical Center, 1998-1999, 2002-2004

Chainnan Dept. of Orthopaedics, St. Mary's Medical Center. 2008-2015

Vice Chief of Staff, Palm Beach Gardens Medical Center, 2000-2002

Vice Chief of Surgery, Palm Beach Gardens Medical Center, 2000-2002

Palm Beach Gardens Medical Center, Medical Council, 2000-2002

Spokesperson, Tenet Southeast Regional Total Joint Program, 1996-2012

Presidential Advisory Council Tulane University 2008- present

Governing Board of Directors Tulane University Medical School 2011-present

## **RESEARCH**

Sanofi Research, Principal Investigator, Phase II and Phase III Clinical Trial, Antithrombotic/DVT prevention in elective primary total hip replacement and revision total hip replacement, 1997-1999.

Organon, Inc., Principal Investigator, Phase III Clinical Trial, Antithrombotic/DVT prevention in elective primary total knee replacement and revision total knee replacement, 1998-1999.

AstraZeneca, Principal Investigator, Phase III Clinical Trial, Antithrombotic/ DVT prevention in elective primary total hip replacement (Protocol 237) and elective primary total knee replacement (Protocol 236 and Protocol 290A and 290B), June 2000-April 2003.

SkyePharma, Inc., Principal Investigator, Phase II/III Clinical Trial, Management of Post-Operative Pain in Patients Undergoing Knee Arthroplasty (Protocol SKY0401-017), June 2002-April 2003.

Bayer Pharmaceuticals, Principal Investigator, Phase II Clinical Trial, Antithrombotic/DVT prevention in elective total knee replacement (Bayer Protocol 10945), May 2004-September 2004.

Endo Pharmaceuticals, Principal Investigator, Phase IV Clinical Trial, Management of Post-Operative Pain in Patients Undergoing Hip Arthroplasty with Regional Anesthesia (Protocol SKY0401-019), August 2004-May 2005.

### **HOSPITAL AFFILIATIONS**

Palm Beach Gardens Medical Center  
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### **REFERENCES**

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EXHIBIT "B" TO EXPERT REPORT OF GEORGE S. KANTOR, M.D. -  
RELIANCE MATERIALS

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All material relied upon in the Expert Witness Report of George S. Kantor, M.D.

1. Algami A, et al. Metallosis-induced Iliopsoas Bursa! Cyst Causing Venous Obstruction and Lower-limb Swelling After Metal-on-metal THA: Case Report. Spotlight on THA. Healio.com/Orthopedics. doi: 10.3928/01477447-20121120-30: 1066-1069.
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8. Bishop, Nicholas, et al. Wear Patterns of Taper Connections in Retrieved Large Diameter Metal-on-Metal Bearings, Journal of Orthopaedic Research, 2013, 1.
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- "Ten-Year Outcome of Serum Metal Ion Levels After Primary Total Hip Arthroplasty: A Concise Follow-up of a Previous Report". *Journal of Bone and Joint Surgery [Am]*, 2013; 95-A(6): 576.
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100. Pagnano M, et al. Patients Preferred a Mini-Posterior Total Hip Arthroplasty Over a Contralateral Two-Incision Total Hip Arthroplasty: Results in Patients Treated with the Same Anesthetic and Rehab Protocol. Paper #11 presented at the AAHKS Fifteenth Annual Fall Meeting.
101. Pagnano M, et al. Two-Incision Total Hip Arthroplasties Had Modest Outcomes and Some Substantial Complications. Paper #10 presented at the AAHKS Fifteenth Annual Fall Meeting.
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133. Internal Biomet documents produced in the litigation or to be produced in the future.
134. Biomet design file produced in the state and federal court litigation.
135. Instructions for Use produced in the litigation by Biomet
136. Mary Bayes' Mercy Medical Center Records and Imaging

137. Mary Bayes' Barnes Jewish West County Records and Imaging
138. Mary Bayes' Des Peres Hospital Records and Imaging
139. Mary Bayes' Barnes Jewish Hospital Records
140. Mary Bayes' York Hospital Records
141. Mary Bayes' McLaren Northern Michigan Hospital Records
142. Mary Bayes' Missouri Baptist Medical Center Records
143. 2013 and 2018 Chromium/Cobalt laboratory results
144. Dr. Paul Lux's May 18, 2012 Letter to Dr. Clohisy Re: Mary Bayes
145. Expert Witness report of Thomas W. Bauer, MD, PhD.
146. Expert Witness Report and Deposition of Thomas Fleeter, MD
147. Intra-Operative photos from March 28, 2011.